PoET Universal Positive Control

Control kit

for use with *PoET Instrument*

For *in vitro* diagnostic use

REF P3M-360-60

IVD CE 0123

Table of contents

1 Intended use

1.1 Intended purpose

PoET Universal Positive Control is a PCR positive control kit of the PoET product line for HCV, HBV, and HIV for professional use for automated *in vitro* testing of human plasma specimens from blood donors.

PoET Universal Positive Control is prepared as a separate reaction. It serves as a qualitative PCR positive control to demonstrate the functionality of the reagents involved in the amplification of the nucleic acids of the virus parameters to be detected.

PoET Universal Positive Control is processed on *PoET Instrument*.

1.2 Intended users

The application has to be carried out by qualified laboratory personnel who have been instructed and trained in *in vitro* diagnostic procedures and have successfully completed the operator's training on *PoET Instrument*.

1.3 Exclusivity

PoET Universal Positive Control is only to be used with *PoET Multiscreen* (REF P2M-28-30).

2 Background

2.1 Test principle

The control kit *PoET Universal Positive Control* has the function of a PCR positive control (PC) and is used in conjunction with the PCR kit *PoET Multiscreen* and *PoET Instrument*.

PoET Universal Positive Control contains a mixture of synthetic nucleic acids of hepatitis C virus (HCV), hepatitis B virus (HBV) and human immunodeficiency virus (HIV). Since the synthetic nucleic acids contained in *PoET Universal Positive Control* correspond to the HCV, HBV, and HIV sequences amplified with *PoET Multiscreen*, the functionality of the PCR kit can be verified.

PoET Universal Positive Control only delivers results in combination with the corresponding PCR kit *PoET Multiscreen.* The qualitative results are part of the automated evaluation of the validity of a PoET run when applying *PoET Multiscreen*. The results are evaluated on the basis of predefined limit values stored in the software *Calliope* of *PoET Instrument* (see Chapter 6.3).

3 PoET system overview

The PoET system provides a fully automated solution for the extraction, amplification and detection of nucleic acids of pathogens in human plasma specimens for applications in high throughput screening or for testing individual samples using nucleic acid amplification technology (NAT). The PoET system consists of a line of different products which are available separately.

PoET system		
PoET Instrument	**PoET reagents**	**Disposables**
	▪ PoET PCR kits ▪ PoET controls ▪ PoET extraction reagents	▪ PCR plates ▪ Extraction plates ▪ Sample tubes ▪ Pipetting tips

4 Reagents

The control kit *PoET Universal Positive Control* contains 60 tubes of *universal positive control* (PC_U v1).

PoET Universal Positive Control	
GFE reference number	P3M-360-60
Basic UDI-DI	42623533729MK
Volume	21,6 mL (60 x 360 µL)

Kit component	**Identifier**	**Primary packaging**	**Reagent ingredients**	**Volume incl. dead volume per kit**
universal positive control	PC_U v1	tube with screw cap (white)	H_2O; tris buffer; tRNA, synthetic nucleic acids	60 x 510 µL

4.1 Reagent storage and handling conditions

Material	**Storage**	**Transport**	**Use**
PoET Universal Positive Control	≤ -18 °C	+2 °C to +25 °C	+15 °C to +30 °C

Upon receipt, store *PoET Universal Positive Control* immediately at ≤ -18 °C.

The reagents are intended for single use.
Any reagents remaining in the tube after application must be discarded.

***PoET Universal Positive Control* is sensitive to light and should be stored protected from light during test preparation.**

Start the analysis on *PoET Instrument* no later than 5 hours after removing the reagents from the storage locations. Do not open the reagents until shortly before starting the run.

Do not use expired reagents. *PoET Instrument* monitors reagent barcodes and will not allow to start a run with expired reagents.

4.2 Additional reagents and disposables required

Material	Reference number
PoET Extraction	P1A-24-04
PoET Prep Reagent	P1B-24-20
PoET Internal Control	P1C-1440-60
PoET Multiscreen	P2M-28-30
PoET Negative Control	P3A-500-30
1000 µL-CO-RE II Tips	235905
300 µL-CO-RE II Tips	235903
Extraction Plate Set	43001-0730
PCR Plate	SP-0362
*13 mL Tube & Cap**	60.541.004 & 65.714

*Optional. Please refer to the operator's manual of *PoET Instrument* for additional information about primary and secondary tubes.

The use of other reagents and disposables on *PoET Instrument* is not permitted.

4.3 Instrumentation and software required

Device	Reference number
PoET Instrument incl. software *Calliope* v2.0 or higher	P9A

5 Warnings and precautions

5.1 General precautions

- Use for *in vitro* diagnostics only.
- Only use in combination with the corresponding PoET PCR kit *PoET Multiscreen* and with *PoET Instrument* as well as the associated reagent kits and disposables.
- Clean and disinfect all work surfaces according to the 'Guideline for Disinfection and Sterilization in Healthcare Facilities' (1) or comparable methods.
- Eliminate potential nucleic acid contamination with DNA-ExitusPlus™ (AppliChem GmbH) or a comparably effective agent according to the manufacturer.
- Treat the specimens as potentially infectious as described in 'Biosafety in Microbiological and Biomedical Laboratories' (2) and CLSI document M29A4 (3). If specimen material is spilled, immediately disinfect with an appropriate agent. Treat contaminated materials as biologically hazardous.
- If spillages of samples or reagents occur on *PoET Instrument*, follow the instructions in the operator's manual of *PoET Instrument* in order to clean and decontaminate its surface.
- Dispose of all materials that have come into contact with potentially infectious specimens and/or reagents, according to the relevant regional and national regulations.
- Material safety data sheets (MSDS) are provided by GFE.
- Wear personal protective equipment (laboratory coat, eye protection, laboratory gloves). Do not eat, drink or smoke in designated work areas.
- Disinfect and wash your hands thoroughly after handling the specimens and reagents, and after removing the gloves. Gloves must be exchanged between handling of specimens, controls and reagents. Avoid contaminating gloves when handling specimens and controls.

5.2 Reagent handling

- Handle all reagents, controls, and specimens according to good laboratory practice in order to prevent carryover of specimens or reagents.
- Store specimens, controls and PCR kits separately.
- Store all reagents, controls and specimens upright and at specified temperatures.
- After receipt, check the integrity of the packaging and the completeness of the product. If there is any evidence of damage, do not use these products for testing.
- *PoET Universal Positive Control* is not shipped on dry ice and may thaw during transportation. Upon receipt, the product must be stored immediately at ≤ -18 °C.
- It must be ensured that there are no drops above the liquid level in the tube before using *PoET Universal Positive Control*.
- PCR reagents are photosensitive. Take care to store and handle the PCR kits and *PoET Universal Positive Control* protected from light sources.
- Avoid interchanging tube caps to prevent cross-contamination.
- It is advisable to place *PoET Universal Positive Control* last on the *PoET Instrument* reagent carrier to avoid contamination of samples or negative controls.
- The reagents are designed for single use. Do not reuse reagent residues in the tube.
- Do not combine different batches of the same reagents.
- Do not use reagents after their shelf life has been expired.

6 Performing the test

PoET Universal Positive Control is a PCR positive control kit of the corresponding PCR kit *PoET Multiscreen*. The test procedure is therefore described in detail in the instructions for use of the PCR kit.

6.1 Requirements for performing the test

- Only personnel trained and qualified as proficient in the use of PoET products and in handling of infectious materials should perform this procedure.
- Closely follow the procedures and guidelines provided to ensure that the test is performed correctly. Any deviation from the procedures and guidelines may affect test performance.
- Use this product only for its intended purpose.
- Use only the specified reagents and disposables.
- Use the product in a temperature range of +15 °C to +30 °C.

6.2 Preparations before use

- In addition to the points described here, observe the instructions for use (IFU) of the other required PoET products.
- Completely thaw the required number of tubes of *PoET Internal Control* at +15 °C to +30 °C before use.
- PCR kits and PCR controls can be loaded on *PoET Instrument* frozen or thawed. Ensure that the duration of storage on the deck of the instrument does not exceed the duration specified in chapter 4.1.
- It must be ensured that no liquid residues adhere to the lids or the tube walls, especially with *PoET Universal Positive Control*.
- *PoET Extraction* and *PoET Prep Reagent* can be used directly.
- Before use, visually inspect each reagent container to ensure that there are no signs of leakage. If there is any sign of leakage, do not use for testing.
- Remove the caps of the reagent tubes and the peel-seal films of the extraction reagent troughs before positioning them on the carriers of *PoET Instrument*. *PoET Instrument* has no device for the automated removal of caps (‘Decapper’) or the piercing of films.
- In order to avoid evaporation of reagents, remove tube caps and peel-seal films only shortly before use. Remove the peel-seal films of the reagent troughs carefully to avoid spilling reagents.
- During positioning of the sample and reagent tubes on the carriers, make sure that the barcode labels are visible through the openings on the side of the carriers. Refer to the operator’s manual of *PoET Instrument* for barcode specifications.
- Carry out the loading and unloading of the *PoET Instrument* reagent carriers as specified in the operator’s manual of *PoET Instrument*.
- Disposables are for one time use only. Do not reuse.
- Please refer to the operator’s manual of *PoET Instrument* for proper instrument maintenance.

6.3 Quality control measures and validity of results

The entire process from sample preparation to PCR analysis is monitored by several controls:

Control type	Product	Function
Internal control (IC)	*PoET Internal Control*	IC is added to each sample at the beginning of the process. For each non-reactive sample, the IC indicates whether the processing from extraction to the result is valid.
PCR positive control (PC)	*PoET Universal Positive Control*	PC are set up as seperate reactions. The PCR positive control contains synthetic nucleic acids of the amplicons of HCV, HBV, and HIV. The PC is used to demonstrate that the reagents involved in the amplification of HCV, HBV, and HIV are functional.
PCR negative control (NC)	*PoET Negative Control*	NC are set up as seperate reactions. The PCR negative control is used to demonstrate that the reagents involved in the amplification reaction are not contaminated with the nucleic acids to be detected.

After the PCR run, the software *Calliope* uses the fluorescence signals to determine the PP and Q values of the PCR reactions. The PP value is similar to the Cq value (quantification cycle) of other PCR evaluation methods, whose output is a natural number (integer, positive number). The PP value is inversely proportional to the amount of template used in the PCR. The higher the quantity, the lower the PP value. The Q value is a measure of the signal/noise ratio of the fluorescence signals. The higher the value, the more PCR products were synthesized during the PCR. PP and Q values therefore represent parameters that are used to evaluate the functionality of a PCR reaction in the PoET system.

Based on the PP and Q values of the controls *Calliope* evaluates, whether the overall result is valid for the sample batch and for each individual sample.

Validation of PCR positive controls (PC)

The PCR positive control *PoET Universal Positive Control* is set up as a separate reaction. The individual reactions are assessed as valid if the PP and Q values are within the limit values for all virus parameters of the respective PCR kits to be detected. With the *PoET Multiscreen* multiplex kit, the PP and Q values for all three virus parameters must be within the limit values for the individual reaction to be assessed as valid. The limit values are stored in the software *Calliope* and were determined by statistical analyses as part of the performance evaluation.

Depending on the sample series, several PCR positive controls for the same virus parameter are prepared on one PCR plate. Whether the overall PC result is valid depends on the result constellation of the individual reactions.

Assessment	Number of PC on a PCR plate per virus parameter	Definition
PC overall result valid	1	PP and Q value of this PC are within the limit values.
PC overall result valid	≥ 2	PP and Q values of all PC are within the limit values.
		PP or Q value of no more than one PC is outside the limit values.
PC overall result invalid	1	PP or Q value of this PC is outside the limit values.
PC overall result invalid	≥ 2	PP or Q values of more than one PC is outside the limit values.

In case of an overall invalid result of the PC, all results of the corresponding sample batch are automatically evaluated as invalid.

The validation of the NC and IC is described in the IFU of the corresponding PoET PCR kit.

6.4 Interpretation of results

Sample results are only valid if the respective PCR controls (PC, NC) of the corresponding sample batch are valid and no processing errors or other malfunctions occurred. A valid sample batch in an individual *PoET Instrument* run may include both valid and invalid sample results. Invalid samples require repeat testing. Valid sample results can be either *reactive* or *not reactive*.
For further details, please refer to the instructions for use of the corresponding PCR kit *PoET Multiscreen.*

6.5 Procedural limitations

- *PoET Universal Positive Control* has been evaluated exclusively for use in combination with *PoET Instrument* and the PCR kit *PoET Multiscreen.*

6.6 Disposal

- PCR positive controls do not contain any hazardous substances.
- Dispose of reagent residues according to the relevant regional and national regulations.
- Dispose of all materials that have come into contact with potentially infectious specimens and/ or reagents, according to the relevant regional and national regulations.

7 Performance characteristics

The control kit *PoET Universal Positive Control* has the function of a PCR positive control (PC) and is used in conjunction with the PCR kit *PoET Multiscreen*, using *PoET Instrument*. The synthetic DNA fragments of the amplicons of the nucleic acids of hepatitis C virus (HCV), hepatitis B virus (HBV) and human immunodeficiency virus (HIV) contained in *PoET Universal Positive Control* were tested for precision and reproducibility.

Metrological traceability

The DNA fragments of *PoET Universal Positive Control* are metrologically traceable to the following WHO International Standards using serial dilution series and a regression analysis with the aid of *PoET Multiscreen* and *PoET Instrument*:

Virus	**WHO International Standard: Version, NIBSC code**
HCV	6th, 18/184
HBV	3rd, 10/264
HIV-1	4th, 16/194
HIV-2	2nd, 16/296

The derivation of quantitative results from the PP values of *PoET Universal Positive Control* does not correspond to the intended use and is therefore not permitted.

Precision and reproducibility

The following table shows the statistical evaluation of the PP values of *PoET Universal Positive Control* with *PoET Multiscreen*. The CV of the PP values range from 0.5 % to 1.9 %.

PoET PCR kit	***PoET Multiscreen***					
Parameter	**HCV**		**HBV**		**HIV**	
Lot *PoET Universal Positive Control*	**Lot 1**	**Lot 2**	**Lot 1**	**Lot 2**	**Lot 1**	**Lot 2**
Number of samples	391	488	391	488	391	488
PP mean value	27,9	27,0	26,1	26,0	25,4	25,0
PP median	28	27	26	26	25	25
Standard deviation	0,3	0,2	0,2	0,2	0,5	0,1
Coefficient of variation (CV)	1,0 %	0,7 %	0,9 %	0,6 %	1,9 %	0,5 %
Upper 95 % confidence interval	28,0	27,0	26,1	26,0	25,4	25,0
Lower 95 % confidence interval	27,9	27,0	26,0	26,0	25,4	25,0

The data, in particular the coefficients of variation of the PP values, confirm the precision and reproducibility of *PoET Universal Positive Control*.

8 Overview of reagents and materials

Reagents	Manufacturer	Reference number	Storage conditions
PoET Extraction	GFE	P1A-24-04	+2 °C to +8 °C, upright
PoET Prep Reagent	GFE	P1B-24-20	+2 °C to +25 °C, upright
PoET Internal Control	GFE	P1C-1440-60	≤ -18 °C
PoET Multiscreen	GFE	P2M-28-30	≤ -18 °C
PoET Negative Control	GFE	P3A-500-30	≤ -18 °C
PoET Universal Positive Control	GFE	P3M-360-60	≤ -18 °C

Material	Manufacturer	Reference number
PoET Instrument incl. software *Calliope* v2.0 or higher	GFE	P9A
1000 µL CO-RE II Tips	Hamilton Bonaduz AG	235905
300 µL CO-RE II Tips	Hamilton Bonaduz AG	235903
Extraction Plate Set	GFE	43001-0730
PCR Plate	Azenta Life Sciences	SP-0362
13 mL Tube & Cap	Sarstedt AG & Co.	60.541.004 & 65.714

Please refer to the operator's manual of *PoET Instrument* for additional information. All items are supplied by GFE.

9 Manufacturer and customer service

Gesellschaft zur Forschung, Entwicklung und Distribution von Diagnostika im Blutspendewesen mbH

Altenhöferallee 3, 60438 Frankfurt am Main, Germany

Phone: +49 (0) 69 / 400 5513 0

Questions concerning PoET products and training courses can be addressed to the local GFE representative:

Web: https://www.gfeblut.de/contact-us/

9.1 Reporting

Inform the local competent authority and GFE if any serious incidents occur when using this product. The summary of the safety and performance report of *PoET Universal Control* can be found using the following link: https://ec.europa.eu/tools/eudamed. Until the EUDAMED database is fully functional, please contact the local GFE representative.

10 Trademarks and patents

- *PoET* and *Calliope* are registered names owned by GFE.
- The *SuperScript® III reverse transcriptase* included in the PCR kits is a product manufactured and licensed by *Life Technologies by Thermo Fisher Scientific*.
- During the application of the PCR kits, the PCR plates (*PCR Plates*)"*FrameStar® 96 (cut corner A12)" with barcode* [Reference number SP0362] are used. These are subject to the following license limitation: "*FrameStar® is covered by one or more of the following US patents or their foreign counterparts, owned by Eppendorf AG: US Patent Nos. 7,347,977 and 6,340,589. FrameStar® is a registered trademark owned by Azenta Life Sciences*".
- Other registered names, trademarks, etc. used in this document are not to be considered legally unprotected, even if they are not specifically marked.

11 References

(1) Rutala WA. Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. 2008;163.

(2) Wilson DE, Chosewood LC. Biosafety in Microbiological and Biomedical Laboratories.

(3) Callihan DR, Clinical and Laboratory Standards Institute. Protection of laboratory workers from occupationally acquired infections: approved guideline. 2014.

12 Symbols

The following symbols are used in labelling of GFE products:

LOT	Batch code	SN	Serial number
REF	Reference number	UDI	Unique device identifier
	GFE manufacturer logo		Manufacturer
YYYY-MM	Use by date (year-month)		Date of manufacture
+Y°C +X°C	Temperature limits	-X°C	Upper temperature limit value
Σ n	Contains sufficient for <n> tests (n = total number of IVD tests)		Caution Indication of safety-related information such as warnings or precautions
	Protect from sunlight		Do not re-use
IVD	*In vitro* diagnostic medical device	www.gfeblut.de	Consult instructions for use (Reference to eIFU)
CE	This device complies with the applicable regulations for CE marking of an *in vitro* diagnostic medical device	CE 0123	CE marking and identification number of the Notified Body (0123)

13 Revision history

Version	Document ID	Date [YYYY-MM-DD]	Remarks
1	IFU-0032	2025-08-13	First release Document template: FB-0122 V02
2	IFU-0032	2025-12-17	- Error correction reference number *Extraction Plate Set* - Editorial changes Document template: FB-0122 V02